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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,905	04/08/2005	Francis Darro	DECLE61.002APC	9936

20995 7590 10/18/2007
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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	**PAPER NUMBER**
1655	

NOTIFICATION DATE	DELIVERY MODE
10/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/530,905	DARRO ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 17* is/are pending in the application.

4a) Of the above claim(s) *8-10* is/are withdrawn from consideration.

5)☒ Claim(s) *13* is/are allowed.

6)☒ Claim(s) *1-7,11,12,14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed July 23, 2007 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. Claim 17 has been added.

3. Claims 1-14, 16, and 17 are pending.

4. In the reply filed on February 6, 2007, applicant elected calotropin and 2' oxo-vorusharin for species A, lung cancer for species B, and vincristine for species C with traverse.

5. Claims 8-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 6, 2007. Paragraph 3 of the last Office action indicated that claims 6 and 7 were withdrawn. However, this was a typographical error. Claims 6 and 7 were examined and rejected as evidenced by the Office action summary and paragraphs 5, 10 and 11 of the Office action.

6. Claims 1-7, 11-14, 16 and 17 are examined on the merits in regards to the elected species.

Claim Rejections - 35 USC § 102/103

7. Claim 14 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hussein et al. (Journal of Chemical Ecology (1994), vol. 20, no. 1, pp. 135-140) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the product claimed by applicant is distinct from the product of Hussein because Hussein does not extract the roots of the Calotropis

procera plant and does not teach that the extract has anti-poisonous activity. The examiner agrees that Hussein does not teach that the extracted is extracted from the roots or has anti-poisonous activity. However, according to applicant's specification, any part of the plant can be extracted using the method of claim 13 and yield a product with anti-poisonous activity. Thus, even though Hussein is not extracting the parts of the plant specifically claimed in claim 13, the method of extraction taught in Hussein is very similar to the method claimed. The reference teaches extracting C. procera by mixing the plant in an aliphatic alcohol, stirring the mixture, and filtering the mixture to obtain and filtrate (filtrate A) and a precipitate. The precipitate is then mixed with alcohol and filtered to obtain filtrate B. Filtrate A and B and then combined together and dried (see page 136 "Isolation of Uscharin"). Due to this close similarity it is reasonable to assume that the extract of C. procera would be chemically the same as the extract produced in claim 13 and would exhibit the same anti-poisonous activity. This is supported by applicant's specification which states that any part of the C. procera plant can be used to extract the anti-poisonous extract. Thus, claim 14 still reasonably appears to be either anticipated or rendered obvious by Hussein.

8. Claim 14 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Alkofahi et al. (Int. J. Crude Drug Res. (1990), vol. 28, no. 2, pp. 139-144) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not anticipate the claimed extract because the reference does not teach that the composition has anti-poisonous properties. However, the reference does teach that the composition has anti-cancer properties

and is extracted using an aliphatic alcohol. According to applicant's specification, the anti-poisonous extracts of C. procera made by extraction with alipathic alcohols are also anti-cancer extracts. Thus, the fact that the reference teaches an anti-cancer extract made by an alipathic alcohol indicates that the reference extract would contain the same chemicals as the currently claimed anti-poisonous extract. Therefore, the reference extract would naturally contain the same anti-poisonous properties because it reasonably appears to be the same extract product.

Claim Rejections - 35 USC § 103

9. Claims 1-7, 11, 12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkofahi et al. (Int. J. Crude Drug Res. (1990), vol. 28, no. 2, pp. 139-144) in view of Sunkara (US Pat. No. 4,904,697) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues the references do not teach the claimed invention because the references do not teach that administration of the C. procera is able to reduce toxic side effects. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The prior art together is considered to teach administering C. procera, vincristine and radiation to treat lung cancer. Thus, the prior art is administering the same treatments as claimed to the same patients as claimed. The prior art is teaching all of the same active steps claimed by applicant. Therefore, the prior art method would intrinsically have to have the toxicity reduced by the C. procera if applicant's invention functions as claimed.

Applicant also argues that none of the references provide for the combined administration of C. procera with vincristine and radiation. However, as discussed in the previous Office action, the prior art shows that all of these treatments were known in the art at the time of the invention to be useful in treating lung cancer. As discussed in MPEP 2144.06:

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, since the prior art teaches that each of the claimed treatments is known to be useful for the same purpose, it is considered obvious to combine these elements together into one treatment.

Applicant argues that the combination of C. procera with the anti-cancer compound produces unexpected results due to the anti-poisonous activity of the C. procera. Applicant argues that the anti-poisonous activity allows for previously fatal doses of the anti-cancer compounds to be utilized. However, applicant's claims do not specify dosages of the anti-cancer compound. Thus, the claims are not commensurate in scope with any potential unexpected results.

Conclusion

10. Claim 13 is allowable. Claims 1-7, 11, 12, 14, 16, and 17 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

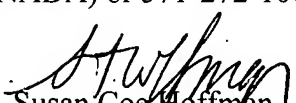
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Susan Coe Hoffman
Primary Examiner
Art Unit 1655